DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Fenbendazole

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Hoechst Roussel Vet. The supplemental NADA provides for establishing tolerances for residues of fenbendazole in edible tissues of cattle. Also, a tolerance for parent fenbendazole in goat muscle is established.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809–4010, filed a supplement to NADA 128–620 that provides for use of Safe-Guard® (fenbendazole) 10% Suspension for Cattle and Panacur® (fenbendazole) 10% Suspension for Cattle. The supplement provides for establishing a tolerance for parent fenbendazole in cattle muscle. The supplement is approved as of May 9, 2000, and the regulations in § 556.275 (21 CFR 556.275) are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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In addition, FDA is reviewing information in the application and it is establishing a tolerance for parent fenbendazole in goat muscle. The regulations are further amended in § 556.275 to reflect this action.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 556 is amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.275 is amended by adding paragraphs (b)(1)(ii) and (b)(3)(ii) to read as follows:

§ 556.275 Fenbendazole.

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(b) * * *

(1) * * *

(ii) *Muscle*. The tolerance for parent fenbendazole (the marker residue) is 0.4 ppm.

* * * * *

(3) * * *

(ii) *Muscle*. The tolerance for parent fenbendazole (the marker residue) is 0.4 ppm.

Dated: June 19, 2000

June 19, 2000

Claire M. Lathers

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Office of New Animal Drug
Evaluation
Center for Veterinary Medicine

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

BILLING CODE 4160–01–F